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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,197	01/23/2002	Joelle Thonnard	BM45399	2955

25308 7590 05/12/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/12/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,197

Applicant(s)

THONNARD, JOELLE

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27,29,32,34,35,38,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,29,32,34,38,43 and 44 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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R sponse to Amendm nt

1. The amendment filed on 2/27/03 has been entered into the record. Claims 27, 38, 43 and 44 have been amended. Claims 27, 29, 32, 34, 35, 38, 43 - 44 are pending in the application
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Priority

3. The Examiner acknowledges the submission of the Priority Document U.K 9918034.1 filed on 7/30/99. Upon further consideration and examination of the priority document, the claims are accorded priority as of the filing date 7/30/99 of the Priority application.

Rejections Withdrawn

4. In view of submission of amendment to the claims, the examiner has withdrawn the rejection under 35 U.S.C. 112, first paragraph is withdrawn.
5. In view of submission of amendment to the claims, the examiner has withdrawn the rejections under 35 U.S.C. 112, second paragraph is withdrawn.
6. The rejection of claims 27, 29, 32 and 34 under 35 U.S.C. 102(a) as being anticipated by Lagace et al 2000 WO 0078968 is withdrawn because the cited reference is no longer applicable as it is published after the filing date of the priority document now of record.

Rejections Maintained

7. The rejection of claims 27, 29, 32, 34, 38, 43 and 44 under 35 U.S.C. 102(b) as being anticipated by Helminen et al 1994 (J.Infec.Dis, 170; 867-872) is maintained as set forth in the previous office action.

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The claims are directed to an isolated polypeptide comprising a member selected from the group consisting of (a) the amino acid sequence SEQ.ID.NO: 2 and (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 wherein the isolated polypeptide, when administered with a carrier induces an antibody or T-cell mediated immune response to a polypeptide having the SEQ.ID.NO: 2. The claims are also drawn to a fusion protein comprising said isolated polypeptide and an immunogenic composition comprising said isolated polypeptide in a pharmaceutically acceptable carrier. The immunogenic composition further comprises one other Moraxella antigen.

Helminen et al, 1994, disclose outer membrane proteins i.e., OMPs prepared from *M.catarrhalis* cells by EDTA buffer method. Monoclonal antibodies were produced by immunizing mice (page 868, left column under production of Mabs) with OMPs. Applicant's use of the open-ended term "comprising" in claim 61 fails to exclude unrecited steps or ingredients and leaves the claims open for inclusion of unspecified ingredients, even in major amounts. Therefore, the claims read on the disclosed isolated polypeptide, OMPs from *M.catarrhalis*. As OMPs comprise many proteins together it would read on fusion protein comprising said peptides and one other Moraxella antigen. Since monoclonal antibodies were raised against OMPs by immunizing the mice with OMPs in a buffer, the examiner considers the OMPs in a buffer as an immunogenic composition comprising said polypeptide in a pharmaceutically acceptable carrier. Therefore, the claimed polypeptides, fusion proteins and immunogenic compositions as claimed are inherent in the preparation of OMPs. See In re Horvitz, 168 F.2d 522, 78 U.S.P.Q. 79 (C.C.P.A. 1948) and Ex parte Davis et al., 80 U.S.P.Q. 448 (PTO d. App. 1948). In the absence of evidence to the contrary the disclosed prior art OMPs read on the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' claimed isolated polypeptide comprising SEQ.ID.NO: 2 with the OMPs of prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicants' arguments filed on 2/27/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that the recited prior art of record does not anticipate the claimed invention and does not disclose any particular polypeptide or much less that of SEQ.ID.NO: 2 as well as associated immunogenic composition and cites MPEP 2131 for support.

It is the position of the Examiner that there is nothing on the record to show the differences between the claimed isolated polypeptide comprising SEQ.ID.NO: 2 and (b) an immunogenic polypeptide comprising a fragment sequence of at least 15 or 20 amino acids that matches an aligned contiguous segment of SEQ.ID.NO: 2 and the disclosed OMPs.

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As OMPs comprise many proteins together it would read on fusion protein comprising said peptides and one other Moraxella antigen as claimed.

Since monoclonal antibodies were raised against OMPS by immunizing the mice with OMPs in a buffer it reads on the claimed immunogenic composition comprising the claimed polypeptide in a pharmaceutically acceptable carrier.

Thus the claimed polypeptides, fusion proteins and immunogenic compositions are inherent in the preparation of OMPS. Therefore, this rejection is maintained.

Applicant states that Helminen et al disclose outer membrane proteins from particular strains of M. catarrhalis.

It is the position of the Examiner that the applicant is arguing a limitation which is not set forth in the claims. Therefore, this rejection is maintained.

Status of Claims

9. Claims 27, 29, 32, 34, 38 and 43-44 are rejected.

Claim 35 is objected to as it depends from a rejected base claim.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will

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be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

5/5/03


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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